APPENDIX A

SEP 2 2 2006

510(K) SUMMARY OF SAFETY AND EFFECTIVINESS

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Date Prepared: August 23, 2006

General Provisions:	Trade Name	ANGIOGUARD™ XP Emboli Capture Guidewire System ANGIOGUARD™ RX Emboli Capture Guidewire System
	Common Name	Embolic Protection Guidewire
	Classification Name	Cardiovascular Percutaneous Catheter (per 21 CFR 870.1250) & Catheter Guidewire (per 21 CFR 870.1330)
	Device-classification	Class II

Predicate Devices: The subject Cordis ANGIOGUARD™ RX Emboli Capture Guidewire System and ANGIOGUARD™ XP Emboli Capture Guidewire System are substantially equivalent to:

- FilterWire ™ EX Embolic Protection System, Boston Scientific Corp.
- PercuSurge GuardWire Temporary Occlusion and Aspiration System, PercuSurge, Inc.

Device Description ANGIOGUARD XP and ANGIOGUARD RX devices consist of a guidewire with an integrated emboli filter at the distal end. The devices function as an interventional guidewire and distal protection device during delivery and placement of the stents and interventional devices during carotid procedures. The devices are delivered via a deployment sheath and captured via a capture sheath. The ANGIOGUARD devices have a filter basket at the distal end that is deployed prior to the stenting procedure. When deployed, the filter basket opens in an umbrella-like fashion, allowing passive hemo-filtration with subsequent emboli capture. At the end of the procedure, the filter is collapsed and retrieved. The device is available with filter basket diameters of 4, 5, 6, 7 and 8mm.

The ANGIOGUARD devices are intended to capture emboli during carotid stenting procedures.

Indications for Use

ANGIOGUARD XP^{M} Emboli Capture Guidewire and ANGIOGUARD RX Emboli Capture Guidewire

The ANGIOGUARD XP Emboli Capture Guidewire and the ANGIOGUARD RX Emboli Capture Guidewire are indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing carotid artery angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of filter basket placement should be from 3mm to 7.5 mm.

Performance Data:

In-vitro testing consisted of dimensional, tensile/torque testing and functional testing. Biocompatibility, sterilization qualification and residual analysis, packaging testing, product shelf-life testing and functional testing in animal models have also been successfully conducted.

Cordis conducted emboli capture and vessel damage studies utilizing an earlier version ANGIOGUARD device; which demonstrated satisfactory results with no significant luminal disruption or hemolysis. Results are applicable to ANGIOGUARD XP and ANGIOGUARD RX, as the basket components of the devices are identical.

Acute studies were conducted on the ANGIOGUARD XP and RX devices to evaluate device performance. Porcine models were used to simulate the anatomy of tortuous human arteries because of the similarity in arterial diameter to human vessels. Results demonstrated satisfactory device performance characteristics.

Clinical Summary

A clinical evaluation in a multi-center, randomized study (SAPPHIRE) was conducted at 29 investigative sites in the United States. The study assessed carotid artery stenting with distal protection, utilizing the Cordis PRECISE® Nitinol Stent System and the ANGIOGUARD XP Emboli Capture Guidewire, as compared to carotid endarterectomy in patients at high-risk for surgery. A separate stent arm was included for patients meeting the entry criteria, but who were determined by the vascular surgeon to be at too high a risk for surgery. Also included was a surgical arm for patients meeting the entry criteria, who the interventionalist determined to be unacceptable candidates for stenting. A total of 334 subjects were entered into the randomized arm of the study (167 stent and 167 CEA patients). A total of 406 subjects were entered into the non-randomized stent arm and 7 subjects were entered into the non-randomized surgical arm. Hence, an overall total of 747 patients were entered into Cordis' pivotal SAPPHIRE study.

Clinical evaluation of ANGIOGUARD XP, together with the preclinical data supporting both ANGIOGUARD XP and RX, was used to provide reasonable assurance of the safety and effectiveness of both devices for the intended clinical indication.

Multicenter clinical data reached the following conclusions:

Randomized Study Arm: The incidence of death, stroke, or MI at 30 days plus death or ipsilateral stroke at 360 days (MAE) in the carotid stent group was 12.0% (20/167) compared with 19.2% (32/167) in the surgical group. In comparing treatment arms for MAE at 360 days, the stent arm was non-inferior to the CEA arm within the designated 3% delta (-7.2% {14.9%, 0.6)]). The difference represented a trend for superiority of the stent arm (p=0.067).

Registry Study Arm: The incidence of death, stroke and MI at 30 days plus death or ipsilateral stroke at 360 days (MAE) was 15.8% (64/406). In a test of the primary endpoint against the OPC, despite the fact that the rate was numerically less than the OPC plus the delta, the p-value was found to be 0.2899. In a test of the MAE rate when post 30-day non-neurological deaths are not included, the p-value was <0.0001. The causes of these non-neurological deaths are well documented and consist of cardiac deaths, cancer deaths, renal failure, and respiratory failure.

The results of the pre-clinical studies and the clinical investigation provide valid scientific evidence and reasonable assurance that the ANGIOGUARD XP and ANGIOGUARD RX devices are safe and effective for their intended use.

Summary of Substantial Equivalence

Cordis Corporation considers ANGIOGUARD XP and RX Emboli Capture Guidewire Systems substantially equivalent to the FilterWire EX Embolic Protection System and Percusurge Guardwire Temporary Occlusion and Aspiration System. All the devices facilitate placement of stents and interventional devices and capture emboli. ANGIOGUARD XP and RX devices and predicate devices are based on 0.014-inch diameter guidewire platforms. ANGIOGUARD XP and RX devices and Boston Scientific's Filterwire EX involve filter-based technology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 2 2006

Cordis Corporation
c/o Ms. Joan Martin
Manager, Regulatory Affairs
7 Powder Horn Drive
Warren, NJ 07059

Re: K062531
ANGIOGUARD™ RX and ANGIOGUARD™ XP Emboli Capture Guidewire Systems
Regulation Number: 21 CFR 870.1250
Regulation Name: Embolic Protection Guidewire
Regulatory Class: Class II (Two)
Product Code: NTE
Dated: August 28, 2006
Received: August 29, 2006

Dear Ms. Martin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number: K062531

Device Name: ANGIOGUARD™ XP Emboli Capture Guidewire System

Indications For Use: The ANGIOGUARD™ XP Emboli Capture Guidewire is indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing carotid artery angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of filter basket placement should be from 3mm to 7.5 mm.

Prescription Use: _X_ AND/OR Over-The-Counter Use: ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Bachman
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K062531